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EXAMINER
FORMAN, BETTY J

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/931,271	DICKINSON ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This action is in response to papers filed 10 March 2003 in which claims 18 and 20 were amended. The amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action dated 5 September 2002 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(b); under 35 U.S.C. 102(e); and 35 U.S.C. 103(a) which are not reiterated below are withdrawn in view of the amendments and/or Applicant's comments. All of the arguments have been thoroughly reviewed and are discussed below. New grounds for rejection necessitated by amendment are discussed.

Claims 1-12 and 15-26 are under prosecution.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) and 120 is acknowledged. However, the Provisional Application filed 10 February 2000 nor Application 09/782,588 filed 12 February 2001 upon which priority is claimed, does not provide adequate support under 35 U.S.C. 112 for claims 1-12 and 15-26 of this application. The instant claims are drawn to an array and method of making the array comprising a rigid support, a molded layer adhered to said rigid support and a layer of bonding agent adhering said rigid support to said molded layer. Neither the Provisional nor the '588 Application provide support for the "adhered" molded layer or the "layer of bonding agent adhering said rigid support" to the molded layer. Therefore, the effective filing date for the instant application is the actually filing date i.e. 16 August 2001.

Comment

3. The above statement is reiterated from the previous office action. In responding to the previous office action, Applicant did not comment on the above statement.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

5. Claims 1-3, 5-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

Regarding Claim 1, Walt et al disclose an array composition comprising a rigid support; a molded layer; with at least a first assay location comprising discrete sites wherein said molded layer is adhered to said rigid support; a layer of bonding agent adhering said rigid support to said molded layer i.e. pattern of adhesive (Column 5, line 49-Column 6, line3 and lines 48-61); and a population of microspheres comprising at least a first and a second subpopulation wherein said first population comprises a first bioactive agent and said second

population comprises a second bioactive agent wherein said microspheres are randomly distributed on said sites (Column 4, lines 35-66).

Regarding Claim 2, Walt et al disclose the array wherein said sites are separated by a distance of at least about 5μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 3, Walt et al disclose the array wherein said sites are separated by a distance of at least about 100μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 5, Walt et al disclose the array wherein said molded layer comprises at least a second assay location (Fig. 5 and 7).

Regarding Claim 6, Walt et al disclose the array wherein said assay locations are separated by a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 7, Walt et al disclose the array wherein said fluid barrier is a physical fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 8, Walt et al disclose the array wherein said physical fluid barrier comprises a material that is added to said molded layer i.e. pattern of adhesive (Column 6, lines 52-61).

Regarding Claim 9, Walt et al disclose the array wherein said molded layer comprises said physical fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 10, Walt et al disclose the array wherein said fluid barrier comprises a physico-chemical surface coating i.e. hydrophobic/hydrophilic functional groups (Column 6, lines 64-66).

Regarding Claim 11, Walt et al disclose the array wherein the bioactive agents comprise nucleic acids (Column 9, lines 41-43).

Regarding Claim 12, Walt et al disclose the array wherein the bioactive agents comprise proteins (Column 8, lines 35-38).

Response to Arguments

6. Applicant argues that the adhesive of Walt et al is not "necessarily" an adhesive for adhering a rigid support to a molded layer as instantly claimed. The argument has been considered but is not found persuasive because the claim is drawn to a composition comprising a rigid support, a molded layer, a layer of bonding agent and a population of microspheres. Walt et al teach the composition. As Applicant notes, the adhesive of Walt et al is not necessarily an adhesive for adhering a rigid support to a molded layer, Walt et al clearly disclose the structural components of the composition.

The courts have stated that claims drawn to an apparatus must be distinguished from the prior art in terms of structure rather than function see *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525,1528 (Fed. Cir. 1990) (see MPEP, 2114).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 4, 15-17 and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349 B1, filed 21 July 1998) and Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998).

Regarding Claim 4, Walt et al teach an array composition comprising a rigid support; a molded layer; with at least a first assay location comprising discrete sites wherein said molded layer is adhered to said rigid support; a layer of bonding agent adhering said rigid support to said molded layer i.e. pattern of adhesive (Column 5, line 49-Column 6, line3 and lines 48-61); and a population of microspheres comprising at least a first and a second subpopulation wherein said first population comprises a first bioactive agent and said second population comprises a second bioactive agent wherein said microspheres are randomly distributed on said sites (Column 4, lines 35-66) and wherein the substrate is comprised of any one of numerous known substrate materials e.g. glass (Column 5, lines 31-47) and the size and shape of the substrate is variable depending on intended use (Column 4, lines 59-64) but they do not specifically teach the substrate is formatted to the dimensions of a microscope slide. However, substrates formatted to the dimensions of a microscope slide were well known in the art at the time the claimed invention was made as taught by Virtanen who teach a similar array composition comprising a rigid support, a molded layer adhered to the rigid support wherein the rigid support is formatted to the dimension of a microscope slide (Column 7, lines 57-59). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the glass substrate of Walt et al and to format the glass substrate to the dimensions of a microscope slide as taught by Virtanen thereby providing a substrate which fits into detection apparatus designed for microscope slides. Based on available equipment, one skilled in the art would have been motivated to format the substrate to the dimensions of a microscope slide for the obvious detecting bioactive agents on the substrate using available equipment.

Regarding Claim 15, Virtanen teaches a method of making an array comprising; contacting a surface of a template structure comprising projections (i.e. stamper) with a moldable material (i.e. disposable film); removing the template (stamp); adhering said molded layer to a rigid support (closing the valves thereby retaining the film on the substrate) (Column 62, lines 1-30 and Fig. 42) wherein the array composition comprises microspheres (Column 5, lines 61-66) and wherein the molded layer is a disposable film which reduces the amount of disposables (Column 62, lines 1-4) but Virtanen does not specifically teach randomly distributing microspheres on said molded layer. However, Walt et al teach a similar method of making an array comprising: providing a patterned surface having an adhesive layer (i.e. patterned adhesive, Column 6, lines 48-61) and further comprising randomly distributing microspheres on said layer such that individual discrete sites comprise microspheres wherein said microspheres comprise at least a first and second subpopulation and wherein said first and second subpopulation comprises a first bioactive agent and a second bioactive agent (Column 4, lines 35-66) wherein the random distribution of microspheres is faster and less expensive that the prior art techniques of spotting and *in situ* synthesis (Column 4, lines 53-56). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the random distribution of microspheres as taught by Walt et al to the assay plate of Virtanen thereby reducing costs and time of providing bioactive agents to the assay plate for the obvious benefits of economy of time and labor as taught by Walt et al (Column 4, lines 53-56). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the molded layer of Virtanen to the array surface of Walt et al thereby providing renewable substrates (Column 7, lines 63-65) and reducing disposables as taught by Virtanen (Column 62, lines 1-4) for the expected benefits providing multiple (renewable) substrates while reducing costs of disposables and disposal.

Regarding Claim 16, Walt et al teach the method wherein said sites are separated by a distance of at least about 5μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 17, Walt et al teach the method wherein said sites are separated by a distance of at least about 100μ m (Column 5, lines 12-17 and Claim 4).

Regarding Claim 19, Virtanen teaches the method wherein the molded layer is flexible i.e. film made of elastic material (Column 62, lines 8-10).

Regarding Claim 20, Virtanen do not teach the molded layer is stored. However, they teach the molded layer is made of thin elastic material (Column 62, lines 8-10). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to store the film of Virtanen in rolled form by rolling the thin film around a solid structure for the obvious benefits of safely and securely storing the thin film.

Regarding Claim 21, Virtanen teaches the method wherein said molded layer comprise at least a second assay location comprising discrete sites (Fig. 42) and Walt et al teach the method wherein said molded layer comprises at least a second assay location (Column 4, lines 59-66).

Regarding Claim 22, Virtanen teaches the method wherein the assay locations are separated by a fluid barrier i.e. wells (Column 62, lines 23-30) and Walt et al teach the method wherein said assay locations are separated by a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 23, Virtanen teaches the method further comprising adding a fluid barrier to said molded layer i.e. stamping to provide wells (Column 62, lines 23-30) and Walt et al teach the method further comprising adding a fluid barrier i.e. wells (Column 5, lines 61-66).

Regarding Claim 24, Virtanen teaches the method wherein the rigid support is formatted to the dimension of a microscope slide (Column 7, lines 57-59).

Regarding Claim 25, Virtanen teaches the method wherein the molded layer is used, disposed of and then replaced with another molded layer to provide a renewable surface (Column 7, lines 63-65) but Virtanen does not specifically teach applying a releasing agent to the surface of the template structure prior to contacting step. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply a

releasing agent to the template based on the fact that the template is removed and reused for the obvious benefits of facilitating removal and reuse of the template.

Regarding Claim 26, Virtanen teaches the method wherein the molded layer is retained on the well plate during assays (Column 62, lines 27-30) but Virtanen does not specifically teach coating the coating the back of the molded layer with an adhering layer. However, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the molded layer of Virtanen by applying an adhering agent to the back of the layer thereby more securely maintaining the layer in the well plate. One skilled in the art would have been motivated to securely maintain the molded layer in the well plate to thereby an array composition which permits assays having rigorous method steps e.g. agitation and/or centrifugation.

Response to Arguments

9. Applicant argues, regarding Claim 4, that neither Virtanen nor Walt et al teach a molded layer that is adhered to a rigid support and a layer of bonding agent adhering the rigid support to the molded layer. The argument has been considered but is not found persuasive for the reasons stated above i.e. the claims are drawn to a composition comprising a rigid support, a molded layer, a layer of bonding agent and a population of microspheres. Walt et al teach the components of the composition. The functional language recited in the claim does not distinguish the claimed composition over that of the prior art.

Applicant argues, regarding Claim 15, that the molded layer of Virtanen, once removed from the template structure loses it structures and as such, no longer forms a molded layer. Applicant has not pointed to support for this teaching in Virtanen. However, in contrast to Applicant's assertion, Virtanen specifically teach molding the moldable material (e.g. Column 62, lines 23-30) wherein the molding (stamping) forms "pits" in the moldable material (Column 3, lines 15-27). While Virtanen may teach an embodiment wherein the moldable material does not retain the molded assay location, this does not negate the fact that Virtanen do specifically

teach embodiments wherein the assay locations are retained i.e. stamped. As such, Virtanen specifically teach molding wherein removing the moldable material from a molded layer comprising discrete sites i.e. pits.

Applicant argues that the examiner has not set forth adequate motivation for combining the references. The argument has been considered but is not found persuasive because, as stated above and reiterated below for Applicant's convenience:

> It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the random distribution of microspheres as taught by Walt et al to the assay plate of Virtanen thereby reducing costs and time of providing bioactive agents to the assay plate for the obvious benefits of economy of time and labor as taught by Walt et al (Column 4, lines 53-56). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the molded layer of Virtanen to the array surface of Walt et al thereby providing renewable substrates (Column 7, lines 63-65) and reducing disposables as taught by Virtanen (Column 62, lines 1-4) for the expected benefits providing multiple (renewable) substrates while reducing costs of disposables and disposal.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, one of ordinary skill in the art of array compositions would have been motivated to combine the teaching of Walt et al and Virtanen thereby reducing costs and time of providing bioactive agents to the assay plate for the obvious benefits of economy of time and labor as taught by Walt et al (Column 4, lines 53-56) and/or thereby providing renewable substrates (Column 7, lines 63-65) and reducing disposables as taught by Virtanen (Column

62, lines 1-4) for the expected benefits providing multiple (renewable) substrates while reducing costs of disposables and disposal.

Applicant argues that because the film of Virtanen does not retain its shape, one of skill in the art would not have been motivated to combine the teaching of Virtanen and Walt et al. The argument has been considered but not found persuasive because as stated above, Virtanen specifically teach molding the moldable material (e.g. Column 62, lines 23-30) and they further teach that their molding technique (stamping) forms "pits" in the moldable material (Column 3, lines 15-27). While Virtanen may teach an embodiment wherein the moldable material does not retain the molded assay location, this does not negate the fact that Virtanen do specifically teach embodiments wherein the assay locations are retained i.e. stamped. As such, Virtanen specifically teach molding wherein removing the moldable material from a molded layer comprising discrete sites i.e. pits.

New Grounds for Rejection Necessitated by Amendment

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349 B1, filed 21 July 1998) and Walt et al (U.S. Patent No. 6,327,410 B1, filed 11 September 1998) as applied to Claim 15 above and further in view of Zager et al (U.S. Patent No. 5,466,319, issued 14 November 1995).

Regarding Claim 18, Virtanen teaches a method of making an array comprising; contacting a surface of a template structure comprising projections (i.e. stamper) with a moldable material (i.e. disposable film); removing the template (stamp); adhering said molded layer to a rigid support (closing the valves thereby retaining the film on the substrate) (Column 62, lines 1-30 and Fig. 42) wherein the array composition comprises microspheres (Column 5,

lines 61-66) and wherein the molded layer is a disposable film which reduces the amount of disposables (Column 62, lines 1-4) but Virtanen does not specifically teach randomly distributing microspheres on said molded layer. However, Walt et al teach a similar method of making an array comprising: providing a patterned surface having an adhesive layer (i.e. patterned adhesive, Column 6, lines 48-61) and further comprising randomly distributing microspheres on said layer such that individual discrete sites comprise microspheres wherein said microspheres comprise at least a first and second subpopulation and wherein said first and second subpopulation comprises a first bioactive agent and a second bioactive agent (Column 4, lines 35-66) wherein the random distribution of microspheres is faster and less expensive that the prior art techniques of spotting and *in situ* synthesis (Column 4, lines 53-56). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the random distribution of microspheres as taught by Walt et al to the assay plate of Virtanen thereby reducing costs and time of providing bioactive agents to the assay plate for the obvious benefits of economy of time and labor as taught by Walt et al (Column 4, lines 53-56). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the molded layer of Virtanen to the array surface of Walt et al thereby providing renewable substrates (Column 7, lines 63-65) and reducing disposables as taught by Virtanen (Column 62, lines 1-4) for the expected benefits providing multiple (renewable) substrates while reducing costs of disposables and disposal.

Virtanen teach the method wherein the template is a stamper as known in the compact disc art (Column 3, lines 10-35) but they do not specifically teach the structure of the stamp. However, Zager et al teach compact disc stampers wherein the stamper is cylindrical and the stamping is via rolling the cylindrical stamp to contact a first portion of the cylinder with the moldable material and then a second portion of the cylinder is contacts the material and removal of the moldable material (Column 10, lines 28-56 and Column 11, lines 21-52). It would have been obvious to one of ordinary skill in the art at the time the claimed invention

was made to apply the cylindrical template stamp of Zagler et al to the stamping of Virtanen et al based on the teaching of Virtanen wherein the stamping is via known compact disc techniques (Column 3, lines 10-35). One of ordinary skill in the art of compact disc-like array would have been motivated to apply the cylindrical stamping of Zagler et al to thereby simultaneously mold and fix the molding based on the teaching of Zagler et al wherein they teach this stamping technique is particularly useful (Column 11, lines 24-26).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
May 27, 2003